some patients. Better criteria for selecting those patients who may benefit from invasive measures are urgently needed, as is critical appraisal of the effects of each measure used. Barbiturate coma, initially introduced as a major advance, may on balance do more harm than good.[7] Even intracranial pressure monitoring, used almost universally in severe cases, has not been shown to lead to improved outcome.

The best cure naturally is prevention. Exciting developments are taking place in this area. Trauner summarizes the evidence linking Reye's syndrome to salicylate use. In the midwestern states an intensive publicity campaign warning against salicylate use for treatment of fever in childhood was started almost three years ago. There is every indication that this has notably influenced the pattern of antipyretic drug use in children. The initial results of this change look encouraging. The incidence of Reye's syndrome in the Midwest has decreased greatly in the past two to three years. In our own institution we have seen only two cases in the past two years, where we would have expected to see 10 to 20. Both had been given salicylates, one for treatment of chronic arthralgia, the other because the mother was unaware that the home remedy she administered to the child contained salicylate as a major ingredient.

Other factors, such as a change in the pattern of viral disease, may explain the recent decrease in the incidence of Reye's syndrome. This large uncontrolled and uncontrollable population study is continuing, with monitoring of case incidence by the state health departments and by the Centers for Disease Control in Atlanta. Every year that Reye's syndrome remains rare where antipyretic use of salicylates is low will increase the likelihood of a cause-effect relationship. At best, there probably will always be some cases of Reye's syndrome, both in children who require salicylates for treatment of chronic illnesses such as juvenile rheumatoid arthritis and, occasionally, in children with high susceptibility in whom exposure to virus alone without the added factor of drug toxicity may precipitate this reaction. In addition, newly introduced drugs may produce new outbreaks of similar syndromes, as is suggested by recent experience with valproic acid.[8]

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On Measuring Both Quality and Costs in Patient Care

THE OBVIOUSLY growing concern with costs in health care and the present emphasis on encouraging competition in this field are already having profound effects. Some may prove to be detrimental while others may bring about improvement. There is also concern that measures to reduce costs may impair the quality of the care rendered. But adequate objective measures of quality in health care have been difficult to come by. All of this has been widely recognized and discussed in both the public and private sectors. So far it has been loudly proclaimed that quality must not be sacrificed but that somehow costs must be contained. The responsibility to accomplish this has been placed on the integrity of the patient's physician to do what is necessary at the least cost and then reliance on peer review of hospital care and of patient care charges to see that this is done. The need for better and more objective approaches to assuring and even improving quality in patient care while responding reasonably to cost considerations is clear enough.

The challenges of the new competition and the imperative to reduce costs combine to require more reliance on objective data in health care. Computers have enormously facilitated this process. For some time now third party insurers, both private and governmental, have had sophisticated computerized data on how, where and by whom health care is rendered. More recently data bases on patient care have developed within many kinds of health care delivery systems including HMOs, IPAs, PPOs and no doubt now in some of the more recent contracting arrangements. The advent of DRGs (so far only for Medicare patients) is now causing hospitals, both for-profit and nonprofit, to hasten to develop objective patient care data to help them and their medical staffs get a better handle on their own health care costs. And one does not need a crystal ball to see that the need for an objective data base for any kind of practice arrangement may not be too far over the horizon. This increasing reliance on objective data bases in health care is one of the profound and far-reaching effects of the growing concern with costs and the present emphasis on competition in health care.

These computerized data bases have been created to measure costs. But could they be used or adapted to measure quality as well? There are some analogies that seem worth considering. Physicians can be quite comfortable with developing data, studying and comparing results, and the principle of peer review. For example, in clinical research data are collected, results are studied and compared, and the findings are subjected to peer review. In the clinical care model new methods and new discoveries are given peer review, data and outcomes are compared, and what is best is introduced into practice. We call this the scientific method. And the experience with accreditation is worth noting. True, here the focus has been more on quality than on costs.

Its method is one of peer review, examination and comparison of data. Its standards of quality are based upon performance data and comparisons between institutions. The accreditation model has proved that over time it can actually raise standards by providing institutions with incentives to move to higher levels of quality. And when one thinks about it, there would seem to be no particular reason why the accreditation model could not be applied to quality of care and cost containment as well. But the point to be made here is that the methods that are coming into being to use patient care data to contain costs may not be all that different from the methods that are needed to develop and use patient care data to measure, assure and even improve quality—and even outcomes—in patient care, while at the same time relating quality, and possibly even outcomes, to costs.

The essential ingredients to measure and assure both quality and costs in patient care seem to be at hand. These include the basic integrity of the vast majority of physicians, the objective data bases that are now developing in every facet of patient care, and the experience with and general acceptance of peer review as a tool to assure quality. Thus it would seem that objective measures for both quality and costs can come from comparisons of objective data to be found in patient care data bases.

Elsewhere in this issue Howard Lang discusses the use of comparisons between services, DRGs, physician performance and the like in terms of costs. All that remains is to use similar or comparable comparisons to assess quality, and then to begin to find ways to relate these assessments of quality to the benefit obtained from the cost. Much of what is needed to do this is already accepted or in place. It is to be hoped that measures such as these comparisons of objective data can be developed and then adopted into general use so as to help meet the challenge of assuring patient care of good quality at affordable cost in these difficult but stimulating times.

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Clinical Application of Biological Research

THE SPECIALTY CONFERENCE, "Recombinant DNA in Medicine," elsewhere in this issue, describes numerous past and recent accomplishments aided by "recombinant DNA" technology and projects their impact on medicine. Although the rubric of "recombinant DNA" could be criticized ("modern biology" might be more appropriate), the introduction of this technology does provide a chronological marker of sorts for an infusion of excitement and rebirth into the field of molecular biology. In reading this article several considerations should be kept in mind. One must realize that "recombinant DNA" technology (or "gene splicing" or "DNA cloning") represents a collection of methodologies that provides a very powerful research tool for many areas of biology and medicine. These methodologies range from microbial genetics and enzymology to the chemical synthesis of DNA and the determination of nucleotide sequences of DNA. To simplify, this technology provides the wherewithal to manipulate, identify and purify segments of DNA from any organism and produce them in substantial quantity for analysis and investigative purposes. In addition, these are the core methodologies for the modern biotechnologic industry, which focuses on the production of useful and commercially viable biological materials or by-products.

In the past ten years since the "recombinant DNA" or "gene splicing" technology was first developed, significant improvements have continually enhanced the efficiency and resolution of molecular biological research. As a result the numerous achievements documented herein include some truly revolutionary discoveries in biology made in the past few years. The discovery of introns in the genes of higher organisms, the documentation of in vivo somatic recombination events as the mechanism for generating antibody diversity, the elucidation of the molecular basis of genetic diseases and the uncovering of a library of oncogenes are but a few examples. One can certainly anticipate further elucidation and understanding of the biological significance of these and other findings. It is equally clear that several other areas of biological interest will be affected by research based on these methodologies. Of particular interest to the medical community will be the thrust into the molecular biological mechanisms of the immune system, and the mysteries of neurobiology and mammalian development.

Notwithstanding the remarkable discoveries made in the past decade, one could ask how many patients have directly benefited from this research. The number must be small. Human insulin is not widely marketed, and only a small number of patients have been treated in clinical trials with the handful of biologicals developed in the biotechnologic industry. Nevertheless, as evidenced in the Specialty Conference in this issue, enthusiasm is widespread in the expectation for significant medical contributions at the patient level. The reason for the delay in direct patient benefits can be illustrated by considering the differences between basic research and the development of a biological product based on the results of basic research. The significant advances in basic research made to date derive from experiments designed to answer questions about biological mechanisms, which in turn generate intellectual constructs. In providing diagnostics or biological materials for the treatment of diseases or genetic disorders, one must first rely on the intellectual constructs as the basis for developing a useful product. The biotechnologists design and engineer an organism that synthesizes the product, and then large-scale production and purification systems must be developed. These processes must be carefully monitored to provide a quality-controlled product. Preclinical data must be gathered to obtain permission to conduct clinical trials. Clinical trials are very expensive and require long trial periods and very long review periods before a final